is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8589 (58 FR 32835, June 14, 1993) and by adding a new airworthiness directive to read as follows:

**ALLIEDSIGNAL INC.:** Docket No. 97–ANE–51–AD. Supersedes AD 93–10–10, Amendment 39–8589.

*Applicability:* AlliedSignal Inc. (formerly Allied-Signal Aerospace Company, Garrett Engine Division and Garrett Turbine Engine Co.) TFE731–2, –3, and –4 series turbofan engines with fuel tubes, part numbers (P/Ns) 3071051–1, 3073729–1, or 3072886–1, installed. These engines are installed on but not limited to the following aircraft: Avions Marcel Dassault Falcon 10, 50, and 100 series; Cessna Model 650, Citation III, VI, and VII; Learjet 31 (M31) 35, 36 and 55 series, Raytheon British Aerospace HS–125 series; and Sabreliner NA–265–65.

**Note 1:** This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent cracked fuel tubes and the subsequent leakage of fuel on and around electrical components, which can cause an engine fire, accomplish the following:

(a) Within 160 hours time in service (TIS) after the effective date of this AD, or prior to December 20, 1999, whichever occurs first, install an improved flexible fuel tube, as follows:

(1) For engines installed on Cessna aircraft, install in accordance with the Accomplishment Instructions of AlliedSignal Inc. Alert Service Bulletin (ASB) No. TFE731–A73–3132, dated April 9, 1997.

(2) For engines installed on all other aircraft except for the Learjet 35, 36 and 55 series, install in accordance with the Accomplishment Instructions of AlliedSignal Inc. ASB No. TFE731–A73–3128, dated February 26, 1997.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles Aircraft Certification Office.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on February 11, 1998.

**James C. Jones,**

*Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 98–4406 Filed 2–20–98; 8:45 am]

BILLING CODE 4910–13–U

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 98–NM–07–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Model A319, A320, and A321 series airplanes. This proposal would require modification of the airplane wiring to separate the electrical inputs sent by the engine interface units (EIU's) to certain probe heat computers (PHC's). This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent simultaneous loss of heating to both pitot probes, which could result in incorrect airspeed indications to both the primary and secondary airspeed indication systems. Loss of these systems could result in reduced controllability of the airplane.

**DATES:** Comments must be received by March 25, 1998.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–07–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

**FOR FURTHER INFORMATION CONTACT:** Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained

in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–NM–07–AD.'' The postcard will be date stamped and returned to the commenter.

**Availability of NPRMs**

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–07–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

**Discussion**

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Airbus Model A319, A320, and A321 series airplanes. The DGAC advises that it received a report indicating that one operator experienced two airspeed discrepancy events due to pitot probes 1 and 3 not heating. The condition originated from isolation defects caused by internal corrosion of probe heat computer (PHC) 3. The existing PHC's 1 and 3 receive the same discrete information from engine interface units (EIU's) 1 and 2 to automatically control the pitot probe heating. This condition, if not corrected, could result in simultaneous loss of heating to both pitot probes, which could lead to incorrect airspeed indications to both the primary and secondary airspeed indication systems. Loss of these systems could result in reduced controllability of the airplane.

**Explanation of Relevant Service Information**

Airbus has issued Service Bulletin A320–30–1036, dated May 9, 1997, which describes procedures for modification of the airplane wiring to separate the electrical inputs sent by the EIU's to PHC's 1 and 3. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The DGAC classified this service bulletin as mandatory and issued French airworthiness directive 97–203–102B, dated August 27, 1997, in order to assure the continued airworthiness of these airplanes in France.

**FAA's Conclusions**

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

**Explanation of Requirements of Proposed Rule**

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

**Cost Impact**

The FAA estimates that 150 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 5 work hours per airplane to accomplish the proposed modification, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $45,000, or $300 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

**Regulatory Impact**

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:

**Airbus Industrie:** Docket 98–NM–07–AD.

*Applicability:* Model A319, A320, and A321 series airplanes, on which Airbus Modification 26403 or Airbus Service Bulletin A320–30–1036 has not been accomplished, certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent simultaneous loss of heating to both pitot probes, which could result in incorrect airspeed indications to both the primary and secondary airspeed indication systems, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 6 months after the effective date of this AD, modify the airplane wiring to separate the electrical inputs sent by the engine interface units (EIU's) to probe heat computers 1 and 3 in accordance with Airbus Service Bulletin A320–30–1036, dated May 9, 1997.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

**Note 3:** The subject of this AD is addressed in French airworthiness directive 97–203–102B, dated August 27, 1997.

Issued in Renton, Washington, on February 13, 1998.

**Stewart R. Miller,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 98–4410 Filed 2–20–98; 8:45 am]

BILLING CODE 4910–13–U

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 349

**[Docket No. 98N–0002]**

**RIN 0910–AA01**

## Ophthalmic Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) ophthalmic drug products. The amendment adds a new warning and revises an existing warning for ophthalmic vasoconstrictor drug products. These products contain the ingredients ephedrine hydrochloride, naphazoline hydrochloride, phenylephrine hydrochloride, or tetrahydrozoline hydrochloride; and they are used to relieve redness of the eye due to minor eye irritations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Submit written comments by May 26, 1998; written comments on the agency's economic impact determination by May 26, 1998. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of March 4, 1988 (53 FR 7076), FDA published a final monograph for OTC ophthalmic drug products in part 349 (21 CFR part 349). That monograph included four ophthalmic vasoconstrictor active ingredients in § 349.18. Section 349.3(i) defines an ophthalmic vasoconstrictor as ''A pharmacologic agent which, when applied topically to the mucous membranes of the eye, causes transient constriction of conjunctival blood vessels.'' Paragraphs (a) and (b) of § 349.75 provide that these products are labeled with the statement of identity ''redness reliever'' or ''vasoconstrictor (redness reliever)'' ''eye'' or ''ophthalmic'' ''insert (dosage form, e.g., drops)'' and with the indication for use ''Relieves redness of the eye due to minor eye irritations.'' Section 349.75(c)(2) requires these products to bear the warning statement: ''If you have glaucoma, do not use this product except under the advice and supervision of a doctor.''

### II. Recent Developments

In the last 3 years, FDA has approved three new drug applications (NDA's) (Ref. 1) for ophthalmic drug products containing pheniramine maleate and naphazoline hydrochloride. These products are used for eye allergy relief to relieve itching and redness of the eye due to pollen, ragweed, grass, animal hair, and dander. These products are not covered by the OTC ophthalmic drug products monograph because the ingredient pheniramine maleate is not included in that monograph.

The agency has received more than 400 adverse drug experience (ADE) reports involving these three products (Ref. 1) in which consumers have reported pupil dilatation (enlarged pupils) after using the eye drops (Ref. 2). Because of the vasoconstrictor action of naphazoline hydrochloride (and the other active ingredients included in § 349.18), pupil dilatation is a known pharmacologic effect of these drugs. The Advisory Review Panel on OTC Ophthalmic Drug Products (the Panel), in its report (May 6, 1980, 45 FR 30002 at 30033), stated that, even at the low concentrations used in OTC drug products, vasoconstrictors occasionally may cause some dilation of the pupil, especially in people who wear contact lens, whose cornea is abraded, or who have lightly colored irides. However, the Panel did not recommend any labeling warning based on this pharmacologic effect of these drugs. The agency also did not include a labeling warning in the past because the enlargement of the pupil(s) is not clinically significant (usually persists for 1 to 4 hours) and does not affect pupil reactivity. As a result, the agency did not mention this pharmacologic side effect in product labeling. Thus, OTC ophthalmic drug products marketed under the monograph or under NDA's do not contain this type of information in their labeling.

The more than 400 ADE reports that have been received have caused the agency to rethink its position on including information about pupil enlargement in the labeling of these OTC vasoconstrictor drug products. The agency now believes that it would be beneficial and informative to consumers to inform them that their pupils may become dilated (enlarged). The agency believes this information in product labeling will reduce the number of ADE reports and will enable consumers to continue using these products and not discontinue use after one or two instillations because they do not expect this pupil enlargement to occur. Accordingly, the agency is proposing to add the following warning in new § 349.75(c)(5) to state: ''Pupils may become dilated (enlarged).''

The agency recognizes that space on OTC ophthalmic drug product labeling is limited, but it considers these additional five words worthwhile because of the number of consumers who have reported this pupil